K080114

丹阳市华一医疗器械有限公司

Danyang Huayi Medical Supply & Equipment Co., Ltd.

SECTION 10.0 SUMMARY OF SAFETY AND EFFECTIVENESS

10.1 ADMINISTRATIVE INFORMATON

10.11 SPONSOR IDENTIFICATION

Danyang Huayi Medical Supply & Equipment, Co. LTD
No. 1 Zhenxing Road, Yunyang
Economical Development Zone
Danyang, Jiangsu, CHINA 212300
Contact Person: Mr. Tomy Tang
e-mail: tomy8034@gmail.com
Telephone: 011- (86511) 8690-0809
Fax: 011-(86511)8690-0805

FEB 15 2008

10.12 ESTABLISHMENT REGISTRATION NUMBER: Pending

10.13 OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph.D.
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, MD 20854
estrin@yourFDAconsultant.com
Tel: (301) 279 -2899
Fax: (301) 294-0126

10.14 DATE OF PREPARATION OF THIS SUMMARY: January 6, 2008

10.15 PROPRIETARY (TRADE) NAME:
Danyang HUAYI H035 Basic Wheelchair

10.16 COMMON NAME: Wheelchair

10.17 CLASSIFICATION N AME: Wheelchair, Mechanical

10.18 REGULATION NUMBERS: 21 CFR 890.3850

10.19 PROPOSED REGULATORY CLASS: Class 1

10.20 DEVICE PRODUCT CODES: 89 IOR

10.21 MEDICAL SPECIALTIES: Physical Medicine

10.3 DESCRIPTION OF DEVICE

The Danyang Huayi H035 Basic Wheelchair is a wheelchair that provides...

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mobility to persons limited to a sitting position. It consists of rigid, mechanical, steel frame and nylon upholstery that meets ISO 7176-16: Resistance to ignition of Upholstered parts. It has two 24" rear wheels and two 8" front casters for turning and maneuverability. The Danyang Huayi H035 wheelchair is intended for use indoors and outdoors, over smooth a surface (all standard indoor flooring surfaces, concrete, asphalt and pocked dirt) that are free of large obstacles and inclines greater than 9 degrees.

10.4 INDI CATIONS FOR USE

The Danyang Huayi H035 Basic Wheelchair is indicated for providing mobility to persons limited to a sitting position.

10.5 CONFOR MANCE TO STANDARDS

The Danyang Huayi H035 Basic Wheelchair production meets the following standards:

- ISO 7176-1 Wheelchair: Determination of static stability
- ISO 7176-3 Wheelchair: Determination of efficiency of brakes.
- ISO 7176-5: Determination of overall dimension, mass and turning space.
- ISO 7176-7: Measurement of seating and wheel dimensions.
- ISO 7176-8 Wheelchair: Requirements and test methods for static, impact and fatigue strengths.
- ISO 7176-11 Wheelchair: Test dummies
- ISO 7176-13: Determination of friction of test surface.
- ISO 7171-15 Wheelchair: Requirements for information disclosure, documentation and labeling.
- ISO 7171-16 Wheelchair: Resistance to ignition of upholstered parts – requirements and test methods.

10.6 PREDIC ATE DEVICE

Access Point Medical, AXS-1 Basic Wheelchair (K050280)

10.7 SUBSTANTIAL E QUIVALENCE

The Danyang Huayi H035 Wheelchair and Access Point Medical AXS-1 Basic wheelchair (K080280) are substantially equivalent products in all areas impacting safety and effectiveness.

10.8 CONCLUSION

The Danyang Huayi H035 Basic wheelchair raises no safety/efficiency issues or makes any claims that differ from the predicate device cited.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 15 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Danyang Huayi Medical Supply & Equipment, Co., LTD.
% Estrin Consulting Group, Inc.
Mr. Norman F. Estrin, Ph.D., President
9109 Copenhaver Drive
Potomac, MD 20854

Re: K080114
Trade/Device Name: Huayi H035 Basic Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: January 3, 2008
Received: January 17, 2008

Dear Dr. Estrin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use

Indications for Use

510(k) Number (if known): _____

Device Trade/Proprietary Name: Danyang Huayi® H035 Basic Wheelchair
Indications for Use:

The Danyang Huayi® H035 Basic Wheelchair is indicated for providing mobility to persons limited to a sitting position.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080114